

SAFETY & EFFECTIVENESS
SUMMARY
CYTOQUANT™ CHLAMYDIA TRANSPORT MEDIUM

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A. SAFETY

According to 21 CFR 866.2900, microbiological specimen collection and transport devices are specimen collecting chambers intended for medical purposes to preserve the viability or integrity of micro-organisms in specimens during storage of specimens after their collection and during their transport from the collecting area to the laboratory. The device aids in the diagnosis of disease caused by pathogenic microorganisms. These devices are classified as Class I (general controls).

Proteins International recommends that the CytoQuant™ Chlamydia Transport Medium be handled at BioSafety Level II with the following precautions taken:

1. Access to the laboratory is limited .
2. All work surfaces are Decontaminated before and after each procedure.
3. Use of automatic pipetting devices is mandatory for all procedures - mouth pipetting is prohibited.
4. Eating, drinking, smoking, and applying cosmetics is not permitted in the laboratory, nor is food stored in the lab areas.
5. Laboratory coats are worn in the laboratory and removed before leaving.
6. Hand washing is required before and after handling transport medium.
7. A class II laminar flow biological safety cabinet is used for all manipulations which may create aerosols whether or not the procedure requires sterility.
8. Contaminated materials are placed in leakproof, autoclavable discard pans filled with distilled water. These pans are closed before removal from the cabinet.
9. Larger plasticware, such as a tissue culture flask, which does not fit in a discard pan, is to be closed and placed in an autoclave bag.
10. All contaminated materials are autoclaved before disposal.
11. Contaminated liquid media collected by vacuum aspiration is inactivated by the addition of bleach to make a 1:15 bleach to media solution, and then discarded.
12. Disposable latex gloves are worn when skin contact with infectious materials is unavoidable or at the discretion of the operator.

Proteins International also has available on request a copy of the MSDS for any antibiotic or antimycotic agent used in the formulation of the medium.

B. EFFECTIVENESS

The CytoQuant™ Chlamydia Transport Medium (2SP) is widely recognized as an effective medium for chlamydia transport (1, 2, 3)

Additionally, Proteins International conducts its own studies on each lot of Chlamydia Transport Medium manufactured, using the following criteria: appearance, sterility, toxicity, and ability of the medium to maintain chlamydia viability over time. Complete

study results for each lot are available on request, as well as suggested QC/QA procedures for those users wishing to perform their own quality testing.

References:

1. Johnson, F. B. 1990. Transport of Viral Specimens. Clin. Microbiol. Rev. 3:120-131
2. Schachter, J. 1986. Chlamydia, p.494. *In*: S. Specter and G. J. Lancz. Clinical Virology Manual. Elsevier, New York.
3. Vera, H. D. and D. A. Power. 1980. Culture media, p 978. *In* E. H. Lennette, A. Balows, W. J. Housler, Jr. and J. P. Truant (Eds). Manual of Clinical Microbiology, 3d Ed. American Society for Microbiology, Washington, D. C.